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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,110	02/15/2001	Maurizio Zanetti	UCSD-07017	2849

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,110

Applicant(s)

ZANETTI, MAURIZIO

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 13-19, 21, 22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 19, 21, 22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/28/05</u> | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed November 28, 2005 in response to the Office Action of June 22, 2005 is acknowledged and has been entered. Previously pending claims 1-12, 20, 23 have been cancelled, claims 19, 21-22 and 24 have been amended and new claims 25-35 have been added. Claims 19, 21-22, 24-35 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 19, 21-22, 24 remain rejected under 35 USC 112, first paragraph and newly added claims 25-35 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 22, 2005, Section 6, pages 3-6.

Applicant argues that cancellation of claims 1-12 which recite the term vaccine and amendment of claim 19 to recite "HLA-A2.1-restricted" overcomes the rejection because the claims DO NOT recite the term vaccine. Further, because Applicant has taught that the exemplary human TRT peptides effectively induce a CTL response after *in vitro* immunization of murine and human peripheral blood mononuclear cells and/or *in vivo* immunization of HLA-A2.1 transgenic mice, Applicant believes that the enablement rejections of the pending claims should be withdrawn.

The arguments have been considered but have not been found persuasive, because although Applicant has cancelled claims 1-12 and the pending claims do not recite the term "vaccine", Applicant is reminded that the claims are read in light of the specification. The specification appears to be drawn only to the use of

the claimed peptides as an anticancer vaccine. It is noted that the invention is entitled "A Universal Vaccine and Method for Treating Cancer Employing Telomerase Reverse Transcriptase". Given the reasons of record, no one would believe it more likely than not that the invention will function as contemplated. The demonstrations of *in vitro* immunization of murine and human PBMCs is not enabling for the reasons of record. The demonstration of immunization of HLA-A2.1 transgenic mice is also not enabling for the reasons of record.

The arguments have been fully considered but have not been found persuasive and the rejection is maintained.

6. Claims 19, 24 remain rejected under 35 USC 112, first paragraph and newly added claims 25-35 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed June 22, 2005, Section 12, pages 13-15.

Applicant argues that cancellation of claim 8 and amendment of the claim to recite "a human telomerase reverse transcriptase peptide" obviates the rejection. The argument has been considered but has not been found persuasive because the

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. If Applicant were able to overcome the rejection set forth above Claims 19, 24, 25-29, 33-36 would still be rejected under 35 USC 112, first paragraph because the specification, while being enabling for peptides consisting of nine amino acids, does not reasonably provide enablement for peptides consisting of from seven to fifteen amino acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a composition for the induction of a cytotoxic T lymphocyte response comprising HLA-A2.1-restricted TRT peptide from seven to fifteen amino acid residues in length. The specification teaches that the majority of peptides bound to MHC class I molecules have a restricted size of 9 +/- 10 amino acids and require free N- and C-terminal ends, that the peptides are most preferentially nine amino acids (published application para 0079) and exemplifies nonamers that stimulate T-cell responses *in vitro* (see Examples).

One cannot extrapolate the teaching of the specification to the scope of the claims because although the specification teaches that the MHC molecule may be a Class I HLA, for example, HLA-2 and that the peptide is from about 7 to about 15 amino acids, RANKPEP: Prediction of MHC-restricted ligands, pgs 1-12 http://mif.dfci.harvard.edu/Tools/rankpep_help.html specifically teaches at page 2 that MHC I ligands are of short length, 9-11 amino acids as they are constrained into the MHC I peptide binding groove, with their N- and C-terminal ends connected by a network of hydrogen bonds to conserved residues of the MHC I molecule. Further, as drawn specifically to HLA-A2.1, Falk et al (Nature, 1991, 290-296, IDS item) specifically teaches that the HLA-A2.1 restricted motif is a nonamer with positions 2 and 9 defined (para bridging pages 292-293 and col 2, 293). Given the art recognition that MHC I ligands are restricted to 9-11 amino acids, that is that positioning is constrained to 9-11 amino acids, given the teaching of one skilled in the art that the specifically claimed HLA-A2.1 restricted motif is a nonamer, cannot be predicted that any motif other than a nonamer would function as claimed or contemplated.

7. Claims 19, 24, 25-29, 33-36 are rejected under 35 USC 112, first paragraph because as the specification does not contain a written description of the claimed

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invention. The limitation of an HLA-A2.1-restricted, human TRT peptide from seven to fifteen amino acid residues in has no clear support in the specification and the claims as originally filed. Applicant points to support for the new claim amendments in original Claims 6, 7 Examples 10-11 and Figure 5. The suggested support has been considered but has not been found persuasive because original claims 6-7 are drawn to human hTRT peptides that are from about 7 to about 15 amino acids with no reference to any HLA molecule, Figure 5 is simply drawn to the hTRT sequence from Nakamura et al, 1997 and Examples 10-11 are drawn to CTL response against nonamer peptides. Thus, the suggested support is not persuasive because the support is not drawn to HLA-A2.1-restricted, human TRT peptides from seven to fifteen amino acid residues. The subject matter claimed in claims 19, 24, 25-29, 33-36 broadens the scope of the invention as originally disclosed in the specification.

8. No claims allowed.

9. All other objections and rejections set forth in the prior office action are hereby withdrawn.

10. Applicant's amendment necessitated the new grounds of rejection drawn to claims 25-35. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE

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OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.



Susan Ungar
Primary Patent Examiner
January 31, 2006